## **EXHIBIT A**

Evaulation of the Tablet Compression properties of various sources of Dextrose Monohydrate

#### **TEST #1**

Applicants prepared three batches of 1185 mg chewable tablets, where 650 mg of dextrose monohydrate from CERELOSE, C\*PHARMDEX 02011, and LYCADEX® PF (Roquette Pharma) were evaluated. The blend was compressed on a Manesty Betapress using 19/32" extra deep concave punches.

Using Corn Products Cerelose, at a compression force of 10.5 KN,

- -tablet hardness = 3.2 kp
- -friability testing of 5 tablets =  $\underline{\mathbf{1} \text{ broke}}$  at  $\underline{\mathbf{97}}$  revolutions, and the  $\underline{\mathbf{4} \text{ others passed}}$   $\underline{\mathbf{100}}$  revolutions

Using **Roquette Lycadex PF**, at a compression force of 10.5 KN,

- -tablet hardness = 2.7 kp
- -friability testing of 5 tablets = **all broke** by **79** revolutions

Using Cerestar CPharm 02010, at a compression force of 10.5 KN,

- -tablet hardness = 1.8 kp
- -friability testing of 5 tablets = **all broke** by **36** revolutions

#### TEST #2

Applicants prepared three batches of 1187.5 mg chewable tablets, where 650 mg of dextrose monohydrate from CERELOSE, C\*PHARMDEX 02011, and LYCADEX® PF (Roquette Pharma) were evaluated. The blend was compressed on a Manesty Betapress using 19/32" extra deep concave punches.

Using Corn Products Cerelose Coarse, at a compression force of 11.5 KN,

- -tablet hardness = 3.6 kp
- -friability testing of 5 tablets =  $\underline{\text{none broke}}$  after  $\underline{50}$  revolutions

Using **Roquette Lycadex PF**, at a compression force of 12 KN,

- -tablet hardness = 1.7 kp
- -friability testing of 5 tablets = 5 of 5 broke after 50 revolutions

Using **Cerestar CPharm 02010**, at a compression force of 12 KN,

- -tablet hardness = 2.1 kp
- -friability testing of 5 tablets = 4 of 5 broke after 50 revolutions

### **EXHIBIT B**

### **MANUFACTURER'S INFORMATION**

## Corn Products U.S.

Cerelose® Coarse Grade Dextrose NF is a dextrose for use as an excipient in pharmaceutical applications and is suitable for direct compression tableting operations.

## **Roquette Lycadex**

### LYCADEX® PF

### Nature's sweet medicine

Dextrose or glucose is the physiological sugar used as an active isotonic agent or a carbohydrate energy source in parenteral infusion or injectable therapies. It is also an essential ingredient in the formulation of peritoneal dialysis and haemodialysis solutions.

These mass medication products can be lifesaving and their quality is critical. The dextrose solutions used in these therapies have to be of the very highest quality.

With LYCADEX® PF, Roquette has pioneered the development of this level of quality in a pyrogen-free Dextrose Monohydrate product that has set a standard recognised around the world.

# Cargill's (Formerly Cerestar) C\*Pharm 02010

monohydrous crystalline D-glucose (dextrose) consisting of multi-granular white crystals.	
C*Pharm 02010 is readily water soluble with a negative he 02010 is characterized by a high nutritive value, excellent assimilation in the human body.	
Moisture Specific rotation Solubility in water (25÷ C)	% 8.3 ÷ 52.9 % d.b 51
	multi-granular white crystals. C*Pharm 02010 is readily water soluble with a negative he 02010 is characterized by a high nutritive value, excellent assimilation in the human body. Moisture

Filterability (35% d.b, 2 bar, 40 C,0.2µ m)
750 ml min
4.5
1500ml min
9

Pyrogens (rabbit test) meets Ph. Eur.III

Endotoxins (LAL test) EU/g (d.s) 0.6

Total bacteria mesophiles CFU/g 1

Total yeasts CFU/g 2

Total moulds CFU/g 1

Applications Parenteral nutrition

Dialysis and serum applications